A post-authorisation safety study of ABRYSVO in immunocompromised, or renally or hepatically impaired adults aged 60 years and older in a real world setting in Europe and UK (C3671038)

First published: 21/02/2025

Last updated: 06/11/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000400

Study ID

1000000400

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Spain

United Kingdom

Study description

As immunocompromised, renally and hepatically impaired older adults were not included in clinical trials that supported regulatory approvals, the safety profile of ABRYSVO in these populations is unknown. This protocol describes a post-authorization safety study (PASS) to assess the safety of ABRYSVO in immunocompromised, or renally or hepatically impaired adults aged 60 and older in select European countries and in the UK, with data sources that can capture vaccine exposure in the target populations, and where outcomes and key covariates can be ascertained.

Study status

Ongoing

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Julius Clinical Research

Netherlands

First published: 02/03/2021

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

University Medical Center Utrecht (UMCU)

☐ Netherlands

First published: 24/11/2021

Last updated: 22/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Analysis Group, Inc.

Networks

Vaccine monitoring Collaboration for Europe (VAC4EU)

☐ Belgium
☐ Denmark
☐ Finland
☐ France
☐ Germany

- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

First published: 22/09/2020

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Network | Outdated | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Cynthia de Luise

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2024

Actual: 01/03/2024

Study start date
Planned: 31/03/2025

Actual: 01/10/2025

Data analysis start date
Planned: 01/11/2028

Date of interim report, if expected
Planned: 30/09/2026

Date of final study report
Planned: 28/09/2029

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer 100%

Study protocol

C3671038_RSV VACCINE OLDER ADULT PROTOCOL V1.0_09JUL2024.pdf

(1016.93 KB)

C3671038_RSV VACCINE OLDER ADULT UPDATED PROTOCOL V2.0_07OCT2024.pdf (1 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

C3671038

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

A retrospective comparative cohort design will serve as the primary study design.

In addition to the primary study design (i.e, comparative cohort design), for an appropriate subset of the study outcomes, the self-controlled risk interval (SCRI) design will also be used.

Main study objective:

To estimate the incidence rates and rate ratios of safety events of interest in immunocompromised, or renally or hepatically impaired adults aged 60 years and older who receive ABRYSVO compared to a relevant comparator group who does not receive ABRYSVO (evaluated as separate populations and if appropriate, as a combined population).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ABRYSVO

Anatomical Therapeutic Chemical (ATC) code

(J07BX05) respiratory syncytial virus vaccines

respiratory syncytial virus vaccines

Population studied

Short description of the study population

The target population will consist of individuals who are immunocompromised, or renally or hepatically impaired (evaluated as separate populations and if appropriate, as a combined population) who are at least 60 years of age on the date of vaccination (i.e, index date for the vaccinated cohort) or on the matched index date (for the unvaccinated cohort), and who have at least 12 months of medical history in one of the data sources with no record of RSV vaccination in that 12 month period and who have at least one day of post-index follow up. Immunocompromised or renally impaired or hepatically impaired status will be ascertained via coded diagnoses, treatments, procedures, and/or laboratory values, as appropriate, at index date or in the 12-month baseline period prior to the index date.

Age groups

- Adults (18 to < 65 years)
- Elderly (≥ 65 years)

Special population of interest

Hepatic impaired

Immunocompromised

Renal impaired

Estimated number of subjects

2356

Study design details

Setting

The study will be conducted in a source population of the participating population-based electronic healthcare data sources from the VAC4EU network.

Comparators

To be included in the unvaccinated cohort, individuals must meet the following criteria:

- No vaccine record on index date: They must not have a record of receiving any vaccine, including the RSV vaccines, on the index date.
- No RSV vaccination in baseline period: They must not have a record of receiving any RSV vaccine during the 12-month baseline before the index date.

For the SCRI design, person-time in the risk interval will be considered “exposed,” while person-time in the control interval will be considered “unexposed.”

Outcomes

Acute disseminated encephalomyelitis; diabetes mellitus type I; Guillain-Barré syndrome; narcolepsy; thrombocytopenia (idiopathic); thrombosisthrombocytopenia syndrome; acute cardiovascular injury; arrhythmia; coronary artery disease; heart failure; microangiopathy; myocarditis and pericarditis; stress cardiomyopathy; coagulation disorders: disseminated intravascular coagulation, venous thromboembolism (pulmonary embolism, deep vein thrombosis), thrombotic microangiopathy, cerebral venous thrombosis, thrombotic thrombocytopenia syndrome, ischemic stroke, myocardial infarction, haemorrhage; single organ cutaneous vasculitis; thrombocytopenia with venous thromboembolism; Bell’s palsy; generalised convulsion; meningoencephalitis; transverse myelitis; acute respiratory distress syndrome; erythema multiforme; anaphylaxis; death (any causes)

Data analysis plan

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed, and maintained by the sponsor and PI.

The SAP may modify the plans outlined in the protocol; any major modifications of primary endpoint definitions or their analyses will be reflected in a protocol amendment.

The SAP will also provide additional detail regarding the evaluation of a threshold of excess risk for each of the outcomes of interest.

This will be determined based on background incidences for each event, in addition to prespecified significance level (e.g., alpha = 0.01 or 0.05) and power. All analyses will be conducted using R version R-4.0.3 or higher.

The SAP will contain additional detail of the data analysis and meta-analysis. One interim analysis and report may be conducted. The interim report will be limited to descriptive analyses. Comparative analyses will be included in the final report. Further details will be described in the SAP.

All analyses will be conducted separately for the 3 populations of interest: immunocompromised, renally impaired, or hepatically impaired; and if appropriate, in the combined population.

Prior to any combined analysis, a Higgin’s I2 statistic will be used to assess the heterogeneity in the primary outcomes across the 3 populations of interest.

If the percentage of heterogeneity estimated by I2 is high (e.g., >50%; specific threshold to be specified in the SAP), a combined effect may be estimated using adapted methods such as a random-effects model.

Documents

Study report

c3671038-progress-report1-report-body.pdf (1.18 MB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Clinical Practice Research Datalink (CPRD) GOLD

The Valencia Health System Integrated Database

The Information System for Research in Primary Care (SIDIAP)

EpiChron Cohort

Système National des Données de Santé (French national health system main database)

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Electronic healthcare records (EHR)

Population registry

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

ConcepTION CDM

CDM website

https://www.imi-conception.eu/

CDM release frequency

6 months

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No